IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO

THEODORE A. HUBBLE, WINONA G. HUBBLE Plaintiff, v. JOHNSON & JOHNSON; ETHICON, INC; ETHICON ENDO-SURGERY, INC; ETHICON ENDO-SURGERY, LLC; and JOHNSON & JOHNSON CONSUMER, INC, Defendants.	)	**Civil Action No.** **COMPLAINT** **DEMAND FOR JURY TRIAL**

COME NOW Plaintiff, Theodore A. Hubble, by and through his undersigned counsel, respectfully alleges to this Court upon information and belief the following:

PARTIES

1. Plaintiff Theodore A. Hubble ("Plaintiff") is a citizen of the State of Texas, residing in Fort Worth, Tarrant County, Texas.

2. Plaintiff Winona G. Hubble is a citizen of the State of Texas, residing in Fort Worth, Tarrant County, Texas.

3. Ethicon Endo-Surgery, Inc. ("Ethicon Endo-Surgery") is incorporated in the State of Ohio and lists its principal office in its current corporate filings with the Secretary of State of Ohio to be at 4545 Creek Road, Blue Ash, Hamilton County, Ohio and has an address registered for service at CT Corporation System, 4400 Easton Commons Way, Suite 125, Columbus, OH 43219. Ethicon Endo-Surgery is a subsidiary of Johnson & Johnson. Ethicon Endo-Surgery therefore is and was at all times relevant to this Complaint a citizen of the State of Ohio and authorized to do business throughout the state. Ethicon Endo-

Surgery is involved in the manufacture, distribution, sales, marketing, regulatory management, and services related to Ethicon medical products in the United States, and in Ohio where it maintains a large sales operation selling Ethicon products all over the states of Ohio and Texas, including the specific Echelon Flex Powered Plus Endopath 60mm Stapler ("Echelon Flex") involved in the subject incident.

4. Ethicon, Inc. ("Ethicon") had at all times relevant to this Complaint its principal place of business at Highway 22, Somerville, New Jersey, 08876 and has an address registered for service with the Ohio Secretary of State at CT Corporation System, 4400 Easton Commons Way, Suite 125, Columbus, OH 43219. Ethicon is a subsidiary of Johnson & Johnson. Ethicon was authorized to do business throughout the state of Ohio. Ethicon was, and its employees were, involved in the manufacture, distribution, sales, marketing, regulatory management, and services related to Ethicon medical products in the United States, and in Ohio where it maintains a large sales operation selling Ethicon products all over the states of Ohio and Texas, including the specific Echelon Flex Powered Plus Endopath 60mm Stapler involved in the subject incident. At all times relevant to this action, Ethicon has conducted substantial business in Ohio.

5. Johnson & Johnson Consumer, Inc. (hereinafter "J&J Consumer") had at all times relevant to this Complaint its principal place of business at 199 Grandview Road, Skillman, NJ 08558. J&J Consumer has an address registered for service with the Ohio Secretary of State at CT Corporation System, 4400 Easton Commons Way, Suite 125, Columbus, OH 43219. J&J Consumer is a subsidiary of Johnson & Johnson. J&J Consumer was authorized to do business throughout the state of Ohio. At all times relevant to this action, J&J Consumer has conducted substantial business in Ohio and regularly caused its products to be sold in Ohio and Texas, including the product at issue in this case. Plaintiffs' causes of action also arise out of specific conduct occurring in the County of Hamilton, State of Ohio.

6. Johnson & Johnson is the parent corporation of the Johnson & Johnson companies, organized and existing under the laws of the State of New Jersey. Johnson & Johnson's principal place of business is at 1

Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Johnson & Johnson has an address registered for service with the Ohio Secretary of State at Terri Johnson, 10219 Salineville Road, Salineville, OH 43945. At all times relevant to this action, Johnson & Johnson has conducted substantial business in Ohio and regularly caused its products to be sold in Ohio and Texas, including the product at issue in this case. Plaintiffs' causes of action also arise out of specific conduct occurring in the County of Hamilton, State of Ohio.

7. Ethicon Endo-Surgery, LLC ("EES") is incorporated in the State of Delaware and its principal place of business is located in Puerto Rico and, per its Certificate of Authorization to do Business of a Foreign Corporation filed with the Puerto Rico Registry of Corporations and Entities, lists its designated office address in Puerto Rico as 475 Street C Los Frailes Industrial Park, Suite 401, Guaynabo, PR 00969 and its Corporate Domicile as 1209 Orange Street, Wilmington, DE 19801. EES has an address registered for service with the Ohio Secretary of State at CT Corporation System, 4400 Easton Commons Way, Suite 125, Columbus, OH 43219. EES is a subsidiary of Johnson & Johnson. At all times relevant to this action, EES has conducted substantial business in Ohio and regularly caused its products to be sold in Ohio and Texas, including the product at issue in this case. Plaintiffs' causes of action also arise out of specific conduct occurring in the County of Hamilton, State of Ohio.

8. Defendants Johnson & Johnson, J&J Consumer Inc., Ethicon, Inc., Ethicon Endo- Surgery, Inc., and Ethicon Endo-Surgery, LLC are hereinafter collectively referred to as "Corporate Defendants" or "Defendants."

9. At all relevant times herein mentioned, the Corporate Defendants, ultimately directed through a direct chain of command from Johnson & Johnson in New Jersey, participated in the promotion and sale of the specific Echelon Flex that is the subject of this case, when they knew, or with the exercise of reasonable

care should have known, of the increased risks, hazards, and unreasonably dangerous propensities, and thereby actively participated in the tortious conduct which resulted in the serious injuries to the Plaintiffs.

10. There exists, as existed at all relevant times herein mentioned, a unity of interest in ownership between Johnson & Johnson and other Defendants such that any individuality and separateness between them has ceased and the Corporate Defendants are the alter ego of Johnson & Johnson and exerted control over the Corporate Defendants. Adherence to the fiction of the separate existence of these certain Defendants as any entity distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction fraud and/or would promote injustice.

11. At all relevant times herein mentioned, the Corporate Defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, testing, manufacturing, producing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling the Echelon Flex device in this case. This device was for use by the Plaintiff and Plaintiff's physicians. As such, each of the Corporate Defendants are individually, as well as jointly and severally, liable to the Plaintiffs for their damages.

12. The harm caused to Plaintiffs resulted from the conduct of one or various combinations of the Defendants, and through no fault of Plaintiffs. There may be uncertainty as to which one or which combination of Defendants caused the harm. Defendants have superior knowledge and information about which one, or which combination caused the injuries.

13. Thus, the burden of proof should be upon each Defendant to prove that the Defendant has not caused the harms suffered by the Plaintiffs.

JURISDICTION AND VENUE

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because the amount in controversy as to each plaintiff exceeds $75,000.00, exclusive of interest and costs, and because complete diversity exists between the parties.

15. This Court has general personal jurisdiction over the Defendants because, at all relevant times, they have engaged in continuous and substantial business activities in this State of Ohio.

16. This Court has general personal jurisdiction because Ethicon Endo-Surgery, a subsidiary of Johnson & Johnson,[1] was at all relevant times incorporated and a citizen of Ohio. Likewise, Ethicon, previously named Johnson & Johnson Medical, Inc.,[2] and J&J Consumer, Inc. are admitted as doing business as foreign corporations in Ohio and have designated an address for service of process in Ohio. One or both Defendants had the power and authority, as well as the obligation, to direct the business operations related to the Echelon Flex Powered Plus Endopath 60mm Stapler in Ohio and Texas.

17. During all relevant times, Ethicon Endo-Surgery engaged in systematic and continuous activity in Ohio to manufacture and sell the Echelon Flex Powered Plus Endopath 60mm Staplers through its subsidiaries, specifically Ethicon Endo-Surgery.

18. During all relevant times, Johnson & Johnson engaged in systematic and continuous activity in Ohio to promote and sell the Echelon Flex Powered Plus Endopath 60mm Staplers through its subsidiaries, specifically Ethicon Endo-Surgery.

19. Further, this Court has specific personal jurisdiction over the Corporate Defendants.[3]

20. At all relevant times, the Corporate Defendants transacted, solicited, and conducted business in Ohio through their employees, agents, and/or sales representatives, and derived substantial revenue from

[1] *Johnson & Johnson Medical Devices Companies* (May 20, 2021), https://www.jnjmedicaldevices.com/en-US/companies/ethicon.
[2] *See Certificate of Amendment to Foreign Licensed Corporation Application*, Ohio Sec. of State (May 8, 2012), https://bizimage.ohiosos.gov/api/image/pdf/201213000045.
[3] *Youn v. Track, Inc.*, 324 F.3d 409, 418 (6th Cir. 2003).

such business in Ohio by marketing the Echelon Flex device to the healthcare providers of the state. As a result, Plaintiffs' claims arise out of Defendants' conduct that occurred in Ohio.

21. The Court also has personal jurisdiction over Ethicon and Ethicon Endo-Surgery because, at all relevant times, Defendants were either present or domiciled in the state and/or consented to jurisdiction in the state by way of registering to do business herein.

22. Jurisdiction in this court is also proper because the Defendants committed torts in whole or in part against the Plaintiffs in the State of Ohio and contracted to supply goods, including the specific Echelon Flex used in Plaintiff's operation which was a defective product, from Ohio to Plaintiff in the state of Texas.

23. As alleged in paragraph 30, the Corporate Defendants herein are unitary, so that jurisdiction over the parent would draw jurisdiction over the subsidiaries.

24. Venue is proper within this District pursuant to 28 U.S.C. § 1391 because it is a judicial district where a substantial part of the events and omissions giving rise to the claims occurred.

FACTS

A. HISTORY OF SURGICAL STAPLERS AND MALFUNCTIONS.

25. Since the early 1900s, surgical staplers have been used in a number of medical operations and procedures.[4]

26. Typically, a stapler is comprised "of the stapler body, a staple cartridge/reload with lines of staplers, an anvil, and a firing mechanism. The surgeon loads a staple cartridge into the stapler (unless they are using

[4] *See* Sophie Childs, *Everything Healthcare Professionals Need to Know about Surgical Staples*, CIA (Apr. 18, 2017), https://www.ciamedical.com/insights/everything-healthcare-professionals-need-to-know-about- surgical-staples/.

a preloaded device) before placing the tissue to be connected between the stapler jaws (comprising of the cartridge and anvil). They then activate the firing mechanism to shoot a staple into place."[5]

27. Innovations in the manufacturing of surgical staplers have led to the creation of staplers for specific procedures.

28. Over the years, surgical staplers have been used to remove a part of an organ (otherwise known as a "resection"), to cut through tissue and organs ("transection"), and to create connections between structures in the body ("anastomoses").[6]

29. The advantages of using surgical staples and staplers include: "Quick placement; Minimal tissue reaction; Low risk of infection; [and] Strong wound closure."[7]

30. Despite their many uses and advantages, surgical staplers also have a long history of malfunctions. For example, by 2004 studies had shown that 112 deaths, 2,180 injuries, and 22,804 adverse events ("AEs") were reported to the FDA connected to surgical stapler use.[8]

31. In fact, one survey found that the incidence rate of stapler malfunction is so high that "86% of laparoscopic surgeons either had personal experience with or knew of surgeons who experienced stapler malfunction."[9]

32. Other studies found that between 8,000 and 9,000 AEs related to surgical staplers occur each year, with 90% of these AEs resulting from a malfunction with the device.[10]

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[5] *Id.*
[6] *Surgical Staplers and Staples*, FDA (June 25, 2019), https://www.fda.gov/medical-devices/general- hospital-devices-and-supplies/surgical-staplers-and-staples.
[7] *Surgical Staplers and Staples*, FDA (June 25, 2019), https://fda.gov/medical-devices/general-hospital-devices-and-supplies/surgical-staplers-and-staples.
[8] *See* S. Lori Brown, *Surgical stapler-associated fatalities and adverse events reported to the Food and Drug Administration*, JACS (May 2004), available at https://www.journalacs.org/article/S1072- 7515(04)00754-9/abstract.
[9] Samwel Okoth Makanyengo and Dhan Thiruchelvam, *Literature Review on the Incidence of Primary Stapler Malfunction, 27 SURG. INNOV., 229-34 (Apr. 2020).*
[10] Sophie Childs, Everything Healthcare Professionals Need to Know about Surgical Staples, CIA (Apr. 18, 2017), https://www.ciamedical.com/insights/everything-healthcare-professionals-need-to-know-about- surgical-staples/.

33. Further, the possible consequences of a malfunction are often very serious. As the FDA explained, "[i]n a retrospective study of 349 colorectal resections using a circular stapler, surgeries with surgical stapler malfunctions were found to have higher incidences of unplanned proximal diversions, ileus, gastrointestinal bleeding, and blood transfusions." Likewise, "[a]nastomotic leaks from surgical stapler malfunctions have also been associated with an increased risk of cancer recurrence."[11]

34. Even if the malfunction does not cause a potentially fatal injury for the patient, such "complications frequently require additional diagnostic studies, invasive procedures and in the need for reoperation resulting in prolonged hospitalization and additional skilled nursing care."[12]

35. As a result of these complications and the ubiquitous malfunctions that have plagued surgical staplers for years, the FDA performed a review of the studies that have been conducted to investigate these issues.[13]

36. After examining these studies, the FDA concluded the most commonly reported malfunctions associated with surgical staplers include malformed staples, missing staples, stapler jamming, and misfires.[14]

37. By 2013, Defendants and the medical device industry in general knew or should have known that malfunctioning surgical staplers presented serious risk of injury during surgery and that the true risk of injury was unknown and unexamined. Despite this obvious problem, these Defendants took no steps to measure of the true risks of these devices much less warn surgeons and their patients of the true risk.

38. Defendants, at all relevant times, were or should have been aware of the dangers a defective surgical stapler posed for patients and should have and were expected to maintain effective procedures to

[11] *FDA Executive Summary*, FDA (May 30, 2019), 11, https://www.fda.gov/media/126211/download.
[12] *Id.* at 9.
[13] Id. at 10.
[14] *Id.* at 10-11.

properly manufacture the Ethicon Stapler and appropriately respond when the Ethicon Stapler was found to be defective.

B. The Ethicon Stapler Recall

39. On October 3, 2019, Defendants issued a Class I recall (the most serious type) of the Echelon Flex Endopath staplers, including the Echelon Flex Powered Plus Endopath 60mm Stapler-340mm shaft, Product Code (PSEE60A) that were manufactured between July 18, 2019 and August 3, 2019 and distributed between July 18, 2019 and August 3, 2019. They recalled 5,733, including this stapler.

40. The stapler contained an out of specification anvil component within the jaw of the device. This condition may lead to malformed staples, which can compromise staple line integrity. If the staple line is compromised, there is a potential risk of prolonged surgery, postoperative anastomotic leak, hemorrhage, hemorrhagic shock, additional surgical intervention, or death.[15]

PLAINTIFFS' SPECIFIC FACTUAL ALLEGATION

41. Plaintiff repeats and incorporates each and every allegation previously set forth herein and further alleges as follows:

42. On or around October 31, 2018, following the discovery of a large ascending colon polyp, Plaintiff Theodore Hubble underwent surgery that included laparoscopic hand-assisted right colectomy.

43. The operative note and hospital supplies records reveal that the Ethicon Stapler was used to create an end-to-end anastomosis, and the Ethicon stapler malfunctioned.

44. On November 5, 2018, Plaintiff Theodore Hubble began to experience complications that were suggestive of an anastomotic leak, the anastomotic leak was confirmed by a CT scan.

[15] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=176700

45. Hubble's surgeon immediately took him into surgery, diagnosing his injury as anastomotic leak with peritonitis. She noted "an approximately 5mm diameter or less defect in the EEA staple line where the ileum met the colon" and "I suspect a mechanical disruption at the staple line".

46. Upon information and belief, Defendants recalled the Ethicon Echelon Flex Powered Plus Endopath 60mm Stapler-340mm shaft, Product Code PSEE60A used during Plaintiff Theodore Hubble's October 31, 2018 surgery.

47. The surgeon took the colectomy down, but he was unable to perform re-anastomosis due to the increased risk of another anastomotic leak. After reinforcing the staple line across the transverse colon and irrigating the previous colectomy area, the surgeon created an end ileostomy.

48. Plaintiff Theodore Hubble remained in the hospital an additional 10 days. During that period, he developed septic shock and postoperative respiratory failure, requiring admission to the intensive care unit, vasopressors, and aggressive fluid resuscitation.

CLAIM I
STRICT PRODUCTS LIABILITY MANUFACTURING DEFECT

49. Plaintiff repeats and incorporates each and every allegation previously set forth herein and further alleges as follows:

50. Pursuant to Ohio Revised Code § 2307.74, "[a] product is defective in manufacture or construction if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards."

51. Further, "[a] product may be defective in manufacture or construction as described in this section even though its manufacturer exercised all possible care in its manufacture or construction."

52. Corporate Defendants used Ethicon Endo-Surgery's principal place of business in Hamilton County, Ohio to promote and sell the Echelon Flex Endopath staplers to medical providers in Ohio, Texas, and other states.

53. Defendants designed, manufactured, inspected, tested, assembled, promoted, distributed, marketed, labeled, and sold the defective stapler used on Plaintiff.

54. At all times material hereto, the defective stapler that was designed, manufactured, inspected, tested, assembled, promoted, distributed, marketed, labeled, and sold by the Defendants, was expected to reach, and did reach, physicians and consumers, including Plaintiff, without substantial change to the condition in which it was sold.

55. At all times material hereto, the stapler that was designed, manufactured, inspected, tested, assembled, promoted, distributed, marketed, labeled, and sold by the Defendants, contained a manufacturing defect, and did not conform to the Defendants' intended design, when it left the Defendants' possession.

56. The manufacturing defect to the Ethicon stapler used in Plaintiff's October 31, 2018 surgical procedure at Texas Health Harris Methodist was a substantial factor in producing Plaintiff's severe injuries

57. The Plaintiff's physician used the Echelon Flex Powered Plus Endopath 60mm Stapler-340mm shaft as directed for its intended purpose.

58. The stapler used in Plaintiff's procedure had not been materially altered or modified prior to its use in Plaintiff.

59. As a direct and proximate result of the wrongful acts and omissions of Defendants, Plaintiffs sustained economic and non-economic damages, permanent injuries, pain and suffering, mental anguish, physical impairment and/or loss of enjoyment of life, physical disfigurement, loss of consortium, loss of

earning capacity and reasonable expenses for necessary medical care, in the past, and in reasonable probability, indefinitely into the future.

CLAIM II
NEGLIGENT PRODUCTS LIABILITY

60. Plaintiff repeats and incorporates each and every allegation previously set forth herein and further alleges as follows:

61. Caselaw in Ohio demonstrates that the Ohio Products Liability Act "has not abrogated the common law applicable to product liability claims."[16] Therefore, a manufacturer may be held liable under both or either the strict liability framework of the Product Liability Act or the framework of a common law negligence action.

62. Defendants had a duty to exercise reasonable care when they designed, manufactured, inspected, tested, assembled, promoted, distributed, marketed, labeled, and sold the stapler, including a duty to ensure that the stapler did not pose a significantly increased risk of adverse events.

63. Defendants failed to exercise reasonable care when they designed, manufactured, inspected, tested, assembled, promoted, distributed, marketed, labeled, and sold the stapler used in Plaintiff's procedure. The stapler used in Plaintiff's colectomy.

64. Defendants failed to exercise reasonable care in the following particulars:

a. Failure to establish and maintain effective quality systems and CGMP's ensuring a defect-free device;

b. Failure to establish and maintain a complaint AE reporting and tracking system that could timely identify and report problems associated with Defendants' devices;

[16] *Boyd v. Lincoln Elec. Co.*, 902 N.E.2d 1023, 1028 (Ohio Ct. App. 2008).

c. Failure to timely notify purchasers, end users, and patients of a defect associated with its curved intraluminal staplers; and

d. Failed to properly warn purchasers, end users, and patients of a defect associated with the stapler that was known or reasonably could have been known at the time of sale

65. In so doing, the Defendants failed to act as a reasonable manufacturer and distributer of surgical staplers.

66. As a direct and proximate result of Defendants' negligence, Plaintiffs have suffered significant damages, and asserts against Defendants, a claim for judgment for all compensatory damages including, but not limited to medical expenses and related costs, extreme physical and mental pain and suffering, mental anguish, disability, disfigurement, degradation, unnecessary loss of personal dignity, and lost earning capacity, in an amount to be determined by the jury, as well as costs and attorneys' fees, plus costs and all other relief to which Plaintiff is entitled by law.

COUNT III
FRAUDULENT MISPREPRESENTATION

67. Plaintiff repeats and incorporates each and every allegation previously set forth herein and further alleges as follows:

"(a) representation or, where there is a duty to disclose, concealment of fact, (b) which is material to the transaction at hand, (c) made falsely, with knowledge of its falsity, or with such utter disregard and recklessness as to whether it is true or false that knowledge may be inferred, (d) with the intent of misleading another into relying upon it, (e) justifiable reliance upon the representation or concealment, and (f) a resulting injury proximately caused by the reliance."[17]

68. Defendants owed legal duties to Plaintiff to disclose important material facts concerning the safety

[17] Carpenter v. Scherer-Mountain Ins. Agency, 733 N.E.2d 1196, 1204 (Ohio Ct. App. 1999) (internal quotation marks and citations omitted).

of the Echelon Flex used in his procedure.

69. Defendants made false representations to Plaintiff and/or Plaintiff's physicians concerning the safety of the Echelon Flex Powered Plus Endopath used in his procedure. Specifically, Defendants intentionally, knowingly, or recklessly without regard for the truth, misrepresented that that the Ethicon used in Plaintiff's procedure was free of any defects, that Defendants were not aware of any defects associated with that device, and that the stapler was a safe and adequate means of performing an anastomosis without unexpected complications and injuries.

70. Defendants made those false representations in an effort to mislead consumers into purchasing and continued use of the stapler and using it for medical procedures, so that Defendants could profit. Through their agents, Defendants directly communicated these misrepresentations to Plaintiff and/or Plaintiff's physicians who were Plaintiff's fiduciaries.

71. At no time prior to the use of Defendants' staplers during Plaintiff's procedure did Defendants acknowledge that the device featured a manufacturing defect rendering it ineffective and unsafe for use in any patient due to an out of specification anvil component within the jaw of the device, despite direct knowledge such risks existing with the device sold to Plaintiff.

72. Defendants' representations to Plaintiff and/or Plaintiff's physicians were false because the stapler was ineffective and unsafe for use in any patient due to the manufacturing defect allowing ejection of malformed staples and uncut washers which could not safely render an anastomosis.

73. Defendants intended medical professionals, including Plaintiff's physicians, and patients to rely on the Defendants' material misrepresentations regarding the safety of the Echelon Flex.

74. Plaintiff and Plaintiff's physicians reasonably relied on Defendants' misrepresentations to Plaintiff's detriment.

75. As a direct and proximate result of Plaintiff and Plaintiff's physicians' detrimental reliance on Defendants' false representations, Plaintiff was injured, and asserts against Defendants, a claim for judgment for all compensatory damages including, but not limited to medical expenses and related costs, extreme physical and mental pain and suffering, mental anguish, disability, disfigurement, degradation, unnecessary loss of personal dignity, and lost earning capacity, in an amount to be determined by the jury, as well as costs and attorneys' fees, plus costs and all other relief to which Plaintiff is entitled by law.

76. Further, in doing the acts herein alleged, the Defendants acted with oppression, fraud, and malice, and Plaintiff is therefore entitled to compensatory damages and, in addition, to punitive damages to deter Defendants and others from engaging in similar conduct in the future. Said wrongful conduct was done with the advance knowledge, authorization and/or ratification of an officer, director and/or managing agent of Defendants.

CLAIM IV
NEGLIGENT MISREPRESENTATION

77. Plaintiff repeats and incorporates each and every allegation previously set forth herein and further alleges as follows:

78. The Defendants had an absolute duty to disclose the true facts regarding the safety of the Echelon Flex as the only entities capable of knowing and reporting the true facts regarding the safety and testing of the Echelon Flex. Furthermore, Defendants had a duty to ensure it had a reasonable basis for making the representations as set forth above.[18]

79. Defendants made false representations to Plaintiff and/or Plaintiff's physicians concerning the safety of the Echelon Flex used in his procedure. Specifically, Defendants intentionally, knowingly, or recklessly

[18] *Delman v. City of Cleveland Heights*, 534 N.E.2d 835, 838 (Ohio 1989) (internal quotation marks and citation omitted).

without regard for the truth, misrepresented that that the Ethicon Echelon Flex used in Plaintiff's procedure was free of any defects, that Defendants were not aware of any defects associated with that device, and that the stapler was a safe and adequate means of performing an anastomosis without unexpected complications and injuries.

80. Defendants made those false representations in an effort to mislead consumers into purchasing and continued use of the Echelon Flex and using it for medical procedures, so that Defendants could profit. Through their agents, Defendants directly communicated these misrepresentations to Plaintiff and/or Plaintiff's physicians who were Plaintiff's fiduciaries.

81. The Defendants made the aforesaid representations with no reasonable ground for believing them to be true. They did not have accurate or sufficient information concerning these representations. Furthermore, Defendants were aware that without such information they could not accurately make the aforesaid representations.

82. At no time prior to the use of Defendants' Echelon Flex during Plaintiff's procedure did Defendants acknowledge that the device featured a manufacturing defect rendering it ineffective and unsafe for use in any patient due to the ejection of malformed staples or uncut washers.

83. Defendants' representations to Plaintiff and/or Plaintiff's physicians were false because the stapler was ineffective and unsafe for use in any patient due to the manufacturing defect allowing ejection of malformed staples and uncut washers which could not safely render an anastomosis.

84. Defendants intended medical professionals, including Plaintiff's physicians, and patients to rely on the Defendants' important material representations regarding the safety of the Echelon Flex.

85. Plaintiff and Plaintiff's physicians reasonably relied on Defendants' misrepresentations to Plaintiff's detriment. During Plaintiff's procedure, the Echelon Flex ejected a malformed staple Plaintiff severe injuries.

86. As a direct and proximate result of Plaintiff and Plaintiff's physicians' detrimental reliance on Defendants' false representations, Plaintiff was injured and asserts against Defendants a claim for judgment for all compensatory damages including, but not limited to medical expenses and related costs, extreme physical and mental pain and suffering, mental anguish, disability, disfigurement, degradation, unnecessary loss of personal dignity, and lost earning capacity, in an amount to be determined by the jury, as well as costs and attorneys' fees, plus costs and all other relief to which Plaintiff is entitled by law.

87. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

CLAIM V
STRICT LIABILITY: FAILURE TO WARN

88. Plaintiff repeats and incorporates each and every allegation previously set forth herein and further alleges as follows:

89. "In a products liability case where a claimant seeks recovery for failure to warn or warn adequately, it must be proven that the manufacturer knew, or should have known, in the exercise of ordinary care, of the risk or hazard about which it failed to warn."[19]

90. "Further, there will be no liability unless it be shown that the manufacturer failed to take the precautions that a reasonable person would take in presenting the product to the public."[20]

91. At all times herein mentioned, the aforesaid product was defective and unsafe in manufacture, and was so at the time it was distributed by Defendants and implanted into Plaintiff.

92. The aforesaid product was defective in that it was not properly prepared and/or was not accompanied by proper warnings regarding all possible adverse side effects associated with the use of the Echelon Flex, and given the severity of the adverse effects, the warnings given did not accurately reflect

[19] *Freas v. Prater Constr. Corp.*, 573 N.E.2d 27, 30 (Ohio 1991).
[20] *Id.* (citation omitted).

the symptoms and severity of the adverse effects

93. The product was also defective in that the product manufactured and distributed differed from the manufacturer's intended results. These defects caused serious injuries to the user when used in its intended and foreseeable manner.

94. The aforesaid product was unaccompanied by warnings of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution. The reasonably foreseeable use of the product, i.e. for use in gastrointestinal operations to create a secure colectomy within the body, involved substantial dangers not readily recognizable by the ordinary user of the product. The Defendants, and each of them failed to warn of the known or knowable likelihood of injury including but not limited to the likelihood the user would develop abscesses, infections, and be forced to undergo corrective operations.

95. The Defendants designed, manufactured, tested, analyzed, distributed, recommended, merchandised, advertised, promoted, supplied, labelled, and sold to distributors the Echelon Flex by Defendants, and each of them, was further defective due to inadequate post-marketing warning or instruction.

96. Plaintiff did not know, nor had reason to know, at the time of the use of the aforesaid product, or at any time prior thereto, of the existence of the foregoing described defects. These defects caused the herein described injuries and damages as herein alleged.

97. The Defendants, and each of them knew that the aforesaid product was to be used by the user without inspection for defects therein and that the aforesaid product was unaccompanied by warnings of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

98. Plaintiff neither knew, nor had reason to know, at the time of the use of the aforesaid product, or at

any time prior thereto, of the existence of the foregoing described defect.

99. As a direct and proximate result of Defendants' failure to warn, Plaintiff was injured, and asserts against Defendants, a claim for judgment for all compensatory damages including, but not limited to medical expenses and related costs, extreme physical and mental pain and suffering, mental anguish, disability, disfigurement, degradation, unnecessary loss of personal dignity, and lost earning capacity, in an amount to be determined by the jury, as well as costs and attorneys' fees, plus costs and all other relief to which Plaintiff is entitled by law.

CLAIM VI
FRAUD BY CONCEALMENAT

100. Plaintiff repeats and incorporates each and every allegation previously set forth herein and further alleges as follows:

101. A common-law fraud claim requires proof of the following elements:

> (a) a representation or, where there is a duty to disclose, concealment of a fact, (b) which is material to the transaction at hand, (c) made falsely, with knowledge of its falsity, or with such utter disregard and recklessness as to whether it is true or false that knowledge may be inferred, (d) with the intent of misleading another into relying upon it, (e) justifiable reliance upon the representation or concealment, and (f) a resulting injury proximately caused by the reliance.[21]

"Ohio courts have consistently recognized "fraud by concealment" or "fraudulent concealment" when the fraud claim raises the issue of concealing a fact when a duty to disclose exists."[22]

102. At all times mentioned herein, Defendants had the duty and obligation to disclose to Plaintiff and to his physicians, the true facts concerning the aforesaid product; that is, that said product was dangerous, and defective, and how likely it was to cause serious consequences to users, including injuries as herein occurred.

[21] *Russ v. TRW, Inc.,* 570 N.E.2d 1076, 1083 (Ohio 1991) (citations omitted).
[22] *Schmitz v. NCAA*, 67 N.E.3d 852, 868 (Ohio Ct. App.) (citations omitted).

103. Defendants made the affirmative representations as set forth above to Plaintiff, his physicians, and the general public prior to the date the Echelon Flex was used on Plaintiff while concealing the following material facts.

104. At all times mentioned herein, Defendants had the duty and obligation to disclose to Plaintiff and to his physicians the true facts concerning the aforesaid product; that is, that use would cause injuries including but not limited to abscesses, infection, and abdominal pain.

Claim VII
LOSS OF CONSORTIUM

105. Plaintiff repeats and incorporates each and every allegation previously set forth herein and further alleges as follows:

106. At all times relevant, Plaintiff Winona G. Hubble was and is the wife of Theodore Hubble.

107. As a direct and proximate result of the previously alleged conduct, Defendants caused injury to Plaintiff Winona Hubble, resulting in Plaintiff losing her rights to the services, assistance, aid, society, companionship, and conjugal relationship between herself and Theodore Hubble.

108. As alleged above, Defendants' conduct, negligence, and recklessness towards and relating to the use of the Echelon Flex on Plaintiff Theodore Hubble resulting in this harm to Winona Hubble.

109. As a direct and proximate result of the injuries and damages suffered by Plaintiff, Plaintiff asserts a claim for judgment for any and all damages to which she may be entitled for the loss of consortium caused by the Defendants, as outlined above, in an amount to be determined by the jury, but in excess of the minimum jurisdictional limits of this Court, plus costs, and to all other relief that Plaintiff is entitled by law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully demand judgment in an amount in excess of the jurisdictional limits in the Southern District of Ohio against all Corporate Defendants, and each of them,

individually, jointly and severally, and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

A) compensatory damages for past, present, and future damages, including, but not limited to, great pain and suffering and emotional distress and anguish, for personal injuries sustained by Plaintiffs, health and medical care costs, together with interest and costs as provided by law;

B) for all ascertainable economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;

C) for specific damages according to proof;

D) for Punitive and Exemplary damages according to proof;

E) for pre-judgment interest and post-judgment interest as allowed by law;

F) for reasonable attorneys' fees;

G) for the costs of these proceedings; and

H) for such other and further relief as this Court deems just and proper.

A JURY TRIAL IS DEMANDED.

Respectfully submitted:

Date: June 25, 2021

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